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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/586,747

06/02/00

BURNETT

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ARMY 105

HM12/1004

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EXAMINER

CRIARES, T

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 10/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/586,747

Applicant(s)

BURNETT ET AL.

Examiner

Theodore J. Criares

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-6,8-10 and 12-14 is/are allowed.
- 6) ☒ Claim(s) 7,11 and 15-33 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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CLAIMS 1-33 ARE PRESENTED FOR EXAMINATION

Claim 2 is objected to since term "antigen" in claim 2, line 2 lacks an antecedent basis in claim 1. Correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable ^{et al.} over Tice (4,389,330).

Present claims 7, 11 and 15-33 recite the term "comprising" which is broader than the phrase "consisting of" as set forth in the original patented claims 1-14. Therefore, present claims 7, 11 and 16-33 are interpreted in their broadest form.

Tice et al teach at column 4, lines 65-67 that the microcapsules of the invention have utility in administering a variety of pharmaceuticals. At column 7, line 35 to column 7, line 49 it is taught how microcapsules of poly(lactide-co-glycolide) microcapsules are formed containing pharmaceutical active agents. At column 5, line 67 to column 6, line 16 Tice et al. teach the antigens that are capable of being formulated in the said microcapsules. At column 4, lines the size of the microcapsules are preferred to be between submicron to 250 um. in size.

The difference between applicants' claims 15-33 from the reference is the mechanism of action recited by the phrase "a conformationally native subunit. . . is exposed to the host immune system. . . pathogen-infected cells." in claim 15.

The quoted phrase is deemed to describe a mechanism of action which would be inherent in the composition formed by the Tice et al reference. See Examples 1 and 2, and claims 1 and 14 of Tice et al.

Claims 16-33 would be redundant since they would be within the scope of claims 1-14 if applicant does not succeed in overcoming the rejection set forth above. It is recognized that applicant's claims 7, 11 and 15-33 are broader than patented claims 1-14. However, Tice et al. teaches and claims applicant's claimed microspheres the difference between the applicant's patented claims and the reference is the term "consisting of" in the patent which is narrower than the term "comprising" of the present claims 7, 11 and 15-33.

For these reasons the claimed subject matter is deemed a prima facie case has been presented and the claims fail to patentably distinguish over the state of the art as

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represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Many of the parent applications were not available and not considered by the examiner at this writing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moeizie can be reached on 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-6897 for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.


Theodore J. Criares
Primary Examiner
Art Unit 1617

T.J.C.
September 28, 2001